

JUN 25 2001

Attachment 16

K011245

510(K) SUMMARY

Pursuant to 510(i) of the Federal Food, Drug, and Cosmetic Act, as Amended.

Company Name:	Sulzer Dental Inc.
Address:	1900 Aston Avenue, Carlsbad, CA 92008-7308
Telephone Number:	760-929-4104
Registration Number:	2023141
Contact Person:	Foster Boop
Date Summary Prepared:	April 16, 2001
Classification Name:	Implant, Endosseous (76DZE)
Common/Usual Name:	Dental Implant System
Device Trade Name:	AdVent™ and SwissPlus™ Dental Implant Systems

The primary devices used for comparison in this summary are the dental implants and indications for use clear under the Branemark System (K992937 and K993595) and the ITI implants (K984104 and K002374).

1. Intended Use:

Sulzer Dental's implant systems are designed for use in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement. The use of the 4.1mm and 4.7mm implant is recommended when the quantity and density of bone would dictate the use of an implant larger than 4.0mm.

Advent and SwissPlus implants have the same intended use as the predicate implants.

2. Description:

AdVent and SwissPlus implants are screw type implants made from titanium alloy or commercially pure titanium. They have the same surfaces as currently available Sulzer Dental implants. The implants are all provided sterile.

3. Technological Characteristics:

There have been no modifications to the AdVent or SwissPlus implants. There has been no change to the implant materials or to the implant/abutment interface.

4. Comparison Analysis:

The overall design of the AdVent and Swiss Plus implants are similar to the predicate implants. See **Table 1** below for a comparison of the Advent and Swiss Plus implants and the predicate devices.

Table 1: Summary of Comparison

Characteristic	Branemark System	ITI Implants	AdVent & SwissPlus
Intended Use	Intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patients chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.	Intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients.	Intended for surgical implantation in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement.
Indication	Immediate Load	Immediate Load	Immediate Load
Design	Threaded, root form implant	Threaded, root form implant	Threaded, root form implant
Placement Method	Two or Single Stage Surgery	Single Stage Surgery	Single Stage Surgery
Material	Commercially Pure Titanium	Commercially Pure Titanium	Commercially Pure Titanium or Titanium alloy
Diameter (mm)	3.75mm and 4.0mm	3.3mm, 4.1mm and 4.8mm	Advent: 3.7mm & 4.1mm Swiss Plus: 4.1mm and 4.8mm
Lengths	10mm – 18mm	8mm – 16mm	AdVent: 8mm – 16mm Swiss Plus: 8mm – 14mm
Implant Surface	Machined Roughened – TiUnite	TPS coated Roughened - Sandblasted Largegrit Acid washed (SLA)	HA coated/Roughened (AdVent only) Or Roughened – HA blasted
Packaging	Glass ampoule in peel-open blister pack	Ampoule	Double vial system
Sterilization	Dry heat	Gamma irradiation	Gamma irradiation



JUN 25 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Foster Boop
Manager of Submissions & Complaints
Sulzer Dental, Incorporated
1900 Aston Avenue
Carlsbad, California 92008-7308

Re: K011245
Trade/Device Name: Advent Implant System, Swiss Plus
Implant System
Regulation Number: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: April 20, 2001
Received: April 23, 2001

Dear Mr. Boop:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

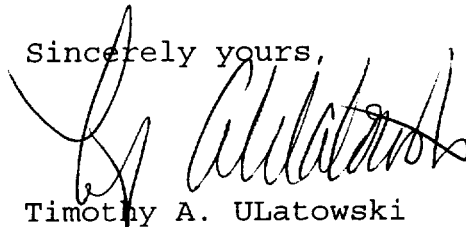
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011245

Page 1 of 1

510(k) Number (if known): K011245

Device Name: AdVent & SwissPlus Dental Implant Systems

Indications For Use:

Advent and Swiss Plus implants are intended for surgical implantation in edentulous or partially edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement.

In patients with an edentulous mandible, AdVent and Swiss Plus implants may be loaded immediately when at least four implants are placed and rigidly splinted with a bar.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Susan Pinner

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number

K011245